UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

HUMANA, INC.,	
Plaintiff,)	Civil Action No.
v.)	21-11578-FDS
BIOGEN, INC. (f/k/a BIOGEN IDEC,	
INC.) and ADVANCED CARE	
SCRIPTS, INC.,	
Defendants.	

MEMORANDUM AND ORDER ON DEFENDANTS' MOTIONS TO DISMISS

SAYLOR, C.J.

This is an action arising out of an alleged scheme to increase the number of prescriptions of drugs used to treat multiple sclerosis ("MS") through improper charitable contributions.

Plaintiff Humana, Inc. is a health-insurance company. Defendant Biogen, Inc. is a biotechnology company and manufacturer of three different drugs used to treat MS. Defendant Advanced Care Scripts, Inc. ("ACS") is a specialty pharmacy company. According to the complaint, Biogen made unlawful donations to different charities to fund patient copays of its MS drugs, thereby increasing the sales of those drugs.

The complaint alleges ten counts: a claim for violation of the civil provisions of the Racketeer Influenced and Corrupt Organizations ("RICO") statute, 18 U.S.C. § 1961 *et seq*. (Count 1); a claim for RICO conspiracy (Count 2); claims under the unfair-competition laws of 22 states (Count 3); claims under the consumer-fraud and deceptive-trade-practice laws of 20 states (Count 4); claims for insurance fraud under the laws of five states (Count 5); breach of

contract (Count 6); tortious interference with contractual relations (Count 7); fraud (Count 8); conspiracy to commit fraud (Count 9); and unjust enrichment (Count 10). Because the counts lump together state-law claims that should have been broken out separately, the complaint in fact asserts 54 claims, only two of which arise under federal law, and the remainder under the laws of 30 different states. Defendants have moved to dismiss the complaint as to all counts.

The complaint is simultaneously over-pleaded and under-pleaded. It is over-pleaded, among other reasons, because it purports to assert 52 state-law claims arising under the laws of 30 different jurisdictions. And it is under-pleaded because it takes a somewhat indifferent approach to the technical requirements of pleading a civil RICO claim and the underlying predicates of mail and wire fraud. The complaint also presents other challenges, including a serious question as to whether it was timely filed.

The principal issue, however, is whether Humana has standing to assert a civil RICO claim. Although Humana was the ultimate payor of the prescription drugs at issue—putting to one side the requirement of a patient copay—it did not purchase the drugs directly from Biogen. Instead, it paid pharmacies for the drugs, who had purchased the drugs from wholesalers or distributors (or possibly from Biogen itself). Humana was thus an "indirect" purchaser.

Under the "indirect purchaser rule," first developed by the Supreme Court in the antitrust context, only a direct purchaser of goods has standing to assert a claim for violation of the antitrust laws. Every circuit to have considered the issue has held that the rule also applies to civil RICO actions, and that indirect purchasers therefore do not have standing to assert RICO claims. The First Circuit has not yet addressed the question. While there may be practical and policy reasons to question the application of that rule in the health-insurance context, for the reasons that follow, this Court will follow the majority rule. It will therefore dismiss the civil

RICO claims for failure to state a claim on that basis. In addition, it will dismiss those claims on the alternate ground that the complaint fails to comply with the technical requirements of the RICO statute and Fed. R. Civ. P. 9(b), and decline to exercise supplemental jurisdiction over the state-law claims.

I. Background

A. Factual Background

The facts are set forth as alleged in the complaint unless otherwise noted.

1. The Parties

Humana, Inc. is a Delaware corporation with a principal place of business in Louisville, Kentucky. (Compl. \P 9). It provides health insurance and prescription drug coverage to more than eight million people in the United States. (*Id.*).

Biogen, Inc. is a Delaware corporation with a principal place of business in Cambridge, Massachusetts. (*Id.* ¶ 12). Among other things, Biogen manufactures Avonex, Tysabri, and Tecfidra, three drugs used to treat MS. (*Id.* ¶¶ 39-45). An annual course of treatment for each of these drugs can cost between \$50,000 and \$80,000 per patient. (*Id.* ¶ 39).

Advanced Care Scripts, Inc. ("ACS") is a Florida corporation with a principal place of business in Cincinnati, Ohio. (Id. ¶ 13). It operates as a specialty pharmacy and provides patient-management services to pharmaceutical companies. (Id.).

2. Other Relevant Entities

The Assistance Fund, Inc. ("TAF") is a Delaware not-for-profit corporation with a principal place of business in Orlando, Florida. (Id. ¶ 14). It provides copay assistance to patients for pharmaceuticals. (Id.).

Chronic Disease Fund, Inc. ("CDF") is a New Jersey not-for-profit corporation with a principal place of business in Frisco, Texas. (Id. ¶ 15). It also provides copay assistance for pharmaceuticals. (Id.).

3. Medicare Parts C and D

Medicare is a government health-insurance program that primarily covers people aged 65 and over and others with certain disabilities or illnesses. (*Id.* ¶ 20). Medicare consists of four parts: A (hospital insurance), B (medical insurance), C (a combination of part A and B coverage that is provided by private insurance companies—referred to as "Medicare Advantage"), and D (prescription drug coverage). (*Id.* ¶ 21). Humana is a provider of Medicare Advantage (Part C) and Medicare Part D insurance plans. (*Id.* ¶¶ 24-25).

Under Medicare Part C, Humana is paid at a capitated rate for each insured. (Id. ¶ 30). Part C plan sponsors do not submit claims directly to the government, although they are subject to various reporting requirements. (Id.).

Premiums for Part D plans are split between insureds and Medicare funds generated by taxpayers. (Id. \P 25). In addition to the cost of premiums, Part D insureds may need to pay for some portion of the cost of their prescription drugs in the form of a copay or deductible. (Id. \P 26). Thus, when a pharmacy dispenses pharmaceuticals to an insured, the individual may need to provide a copay. (Id.). The pharmacy then submits a reimbursement claim to the insurer (here, Humana) for the remaining portion of the drug cost. (Id. \P 27).

4. The Scheme

According to the complaint, Biogen and ACS engaged in a two-part scheme with TAF and CDF that caused both the number of prescriptions and the price of the MS drugs to increase and, in turn, caused Humana to overpay for those drugs. (*Id.* ¶ 1-3).

In the first part of the alleged scheme, Biogen would "seed" the market. (Id. \P 2). In

order to increase the use of the MS drugs throughout the market, Biogen would provide free drugs to patients who lacked insurance coverage or whose coverage did not extend to its MS drugs. (*Id.* ¶¶ 46, 51). According to the complaint, this is because once a patient starts a particular therapy, he or she is more likely to continue that therapy. (*Id.* ¶ 46). The complaint alleges that Biogen did this because it anticipated that a large portion of patients in its free-drug program would eventually enroll in a government or private drug-coverage program, and this would enable it to make a profit on the insurance reimbursements for its MS drugs. (*Id.* ¶ 54).

In the second part of the alleged scheme, Biogen worked with TAF and CDF to move patients from its free-drug program into Medicare. (*Id.* ¶¶ 47, 56-70). To do this, Biogen's Patient Services Department ("PSD"), or a third party, identified which patients in the free-drug program were eligible for Medicare. (*Id.* ¶ 59). The PSD would then contact eligible patients to obtain their consent to being enrolled in the government-funded program. (*Id.*).

To keep the MS drugs affordable for patients (and, therefore, increase the likelihood that they continue treatment with the MS drugs), Biogen allegedly coordinated with CDF and TAF to enroll patients using the MS drugs into their patient-assistance programs ("PAPs"). (*Id.* ¶¶ 47, 60). PAPs cover drug copayments for patients. (*Id.*). According to the complaint, Biogen would make grant donations to CDF and TAF in exchange for their commitment to enroll patients using the MS drugs into their PAPs. (*Id.* ¶ 60). After receiving Biogen's grant donations, the PAP would approve the applications of MS drug patients and cover the costs of their copays. (*Id.* ¶ 64). Medicare insurers such as Humana would then reimburse Biogen for the remaining portion of the drug cost that was not paid. (*Id.*). The complaint alleges that Biogen tracked every prescription and knew precisely which Medicare prescriptions were covered by a PAP. (*Id.* ¶ 61).

The complaint alleges that Biogen also coordinated its donations to the PAPs through ACS. (*Id.* ¶¶ 64-68). It alleges that ACS would transfer patients using the MS drugs from Biogen's free-drug program to a PAP. (*Id.*). Using specific information provided by Biogen about its Medicare-eligible patients currently using MS drugs, ACS would send a "batch file" of that patient information to the PAPs. (*Id.*). The complaint alleges that ACS participated in the scheme because it derived revenue from transitioning patients to the PAPs and filling prescriptions of the MS drugs through its specialty pharmacy. (*Id.* ¶ 70).

The complaint alleges that Humana incurred significant losses because of Biogen's scheme to inflate the price and use of its MS drugs. (*Id.* ¶ 81). It alleges that Biogen and ACS provided false certifications asserting that they were complying with federal and state law, including the Anti-Kickback Statute and False Claims Act. (*Id.* ¶¶ 35, 83, 132). It alleges that from 2011 to 2019, Humana paid more than \$1.9 billion for prescriptions of the MS drugs, with ACS accounting for nearly \$350 million of that spending. (*Id.* ¶ 84).

B. Procedural Background

On September 24, 2021, Humana filed this action against Biogen and ACS. As noted, the complaint asserts ten counts, two of which arise under the civil RICO statute, 18 U.S.C. § 1964(c), and the remainder under various state laws.

Defendants have moved to dismiss the complaint as to all counts, contending that all of the claims are time-barred and the complaint fails to state a claim upon which relief can be granted under Fed. R. Civ. P. 12(b)(6).

II. Standard of Review

To survive a motion to dismiss, the complaint must state a claim that is plausible on its face. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In other words, the "[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the

assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). When determining whether a complaint satisfies that standard, a court must assume the truth of all well-pleaded facts and give the plaintiff the benefit of all reasonable inferences. *See Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). Dismissal is appropriate if the complaint fails to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008) (quoting *Centro Médico del Turabo, Inc. v. Feliciano de Melecio*, 406 F.3d 1, 6 (1st Cir. 2005)).

III. Analysis

A. Statute of Limitations

Defendants first contend that all claims, both federal and state, are barred by the applicable statutes of limitations.

RICO has a four-year statute of limitations. *Agency Holding Corp. v. Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 152 (1987). The state-law claims are subject to a variety of different statutes of limitations; it appears that the longest potentially applicable period is six years. *See, e.g.*, Mass. Gen. Laws ch. 260, § 2.

The complaint in this action was filed on September 24, 2021. It does not allege that defendants took any actions within the preceding four years (that is, after September 24, 2017). Instead, it alleges that defendants undertook a variety of different acts in furtherance of the scheme to defraud, the latest of which occurred at "the end of 2014 and beginning of 2015." (Compl. ¶ 77). Exhibit A to the complaint, which is captioned "Examples of 100 Biogen

Subsidized Copayments," lists various payments made between January 7, 2011, and March 23, 2016. Accordingly, all of the federal claims, and most (if not all) of the state claims, are timebarred unless (1) the claims accrued at a later date or (2) equitable tolling of the limitations period applies.¹

Humana contends that under the discovery rule, its claims did not accrue, and the limitations period did not begin to run, until December 17, 2020, when the Department of Justice settlement was unsealed. (Compl. ¶ 87). It further contends that the running of the limitations period should be equitably tolled under the fraudulent concealment doctrine.

1. The Discovery Rule

Under federal law, the limitations period begins to run from the time "when a plaintiff knew or should have known of his injury." *Rotella v. Wood*, 528 U.S. 549, 553 (2000); *Álvarez-Maurás v. Banco Popular of Puerto Rico*, 919 F.3d 617, 625 (1st Cir. 2019). Once there are "sufficient facts . . . available to provoke a reasonable person in the plaintiff's circumstances to inquire or investigate further," the plaintiff is on "inquiry notice" of his or her claims. *McIntyre v. United States*, 367 F.3d 38, 51-52 (1st Cir. 2004); *see also Álvarez-Maurás*, 919 F.3d at 626 (stating that a plaintiff "should know" of an injury when there are "storm warnings" that would put a reasonable plaintiff on "inquiry notice"); *Sanchez v. United States*, 740 F.3d 47, 52 (1st Cir. 2014) ("To delay commencement of the running of the statute of limitations, the factual basis for the cause of action must have been inherently unknowable [that is, not capable of detection through the exercise of reasonable diligence] at the time of injury." (alteration in original) (cleaned up)). A plaintiff on inquiry notice is "charged with the knowledge of what he or she

¹ Humana does not contend that the wrongful activity continued beyond September 2017, under a "continuing tort" theory or otherwise. *See Dagi v. Delta Airlines, Inc.*, 961 F.3d 22, 30 n.9 (1st Cir. 2020).

would have uncovered through a reasonably diligent investigation." McIntyre, 367 F.3d at 52.

Inquiry notice focuses on the injury itself, not the other elements of a potential claim. *See Rotella*, 528 U.S. at 555 ("[D]iscovery of the injury, not discovery of the other elements of a claim, is what starts the clock."); *Kennedy v. Josephthal & Co.*, 814 F.2d 798, 802 (1st Cir. 1987) ("Inquiry notice is triggered by evidence of the possibility of fraud, not full exposition of the scam itself."). Thus, in a RICO case, the limitations period will begin to run even if the plaintiff has not discovered "the underlying RICO pattern." *Rotella*, 528 U.S. at 557.

The standard is objective—that is, whether the information available to a reasonable person in plaintiff's position would have "provoke[d]" that person "to inquire or investigate further." *McIntyre*, 367 F.3d at 52. Accordingly, in appropriate circumstances, the issue of accrual may be decided on a motion to dismiss or for summary judgment.

Humana argues that the claim did not accrue when it was on inquiry notice, but only after it had developed sufficient information to file a complaint. (Pl. Opp. at 12 (arguing that a claim accrues "not when a plaintiff has enough information to begin an investigation, but rather enough facts on which to plead a viable complaint.")). But that argument conflates the inquiry standard (whether a plaintiff is on sufficient notice that he or she should begin an investigation) with the Rule 11 pleading standard (whether the plaintiff has a good-faith basis to file a complaint). And that is not the law of this circuit.²

Defendants have submitted hundreds of pages of material—including media reports, government filings, and SEC filings by Biogen—suggesting that Humana was, or reasonably should have been, on inquiry notice of a potential claim by 2016 at the latest. Those materials

² To the extent that the opinion in *Massachusetts Mutual Life Insurance Co. v. DB Structured Products, Inc.*, 2015 WL 3964560, at *8 (D. Mass. June 19, 2015) suggests otherwise, this Court respectfully disagrees with that conclusion.

are outside the pleadings, which normally means that the court may not consider them in resolving a motion to dismiss. *See* Fed. R. Civ. P. 12(d).

It is true that the court may, in its discretion, consider documents outside the pleadings where there is no dispute as to their authenticity. *Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co.*, 267 F.3d 30, 33 (1st Cir. 2001). It is also true that Humana does not dispute the authenticity of those items (although it disputes what inferences may be reasonably drawn from them). Nonetheless, the Court will not resolve the issue on the pleadings.

As is set forth below, the complaint fails to plead fraudulent concealment with the requisite specificity. Even so, as Humana notes, this case does not involve obviously "self-revealing" injuries, such as an investment loss or a personal injury. (Pl. Opp. at 2). When Humana was placed on inquiry notice may therefore involve a substantial factual question, centering on what the corporation knew or reasonably should have known about a potential injury. Because it is a large (and presumably sophisticated) corporation, that knowledge might have been gleaned from multiple sources, in multiple ways. And that might be true even if no one corporate employee had the requisite knowledge; under the "collective knowledge" doctrine, the "knowledge" attributable to a corporation is normally the sum of all of the knowledge possessed by all of its employees, regardless of their position. *See United States v. Bank of New England, N.A.*, 821 F.2d 844, 856 (1st Cir. 1987).

In any event, whether Humana was on inquiry notice at some point prior to September 24, 2017, is a fact-intensive question that is best resolved, at a minimum, on a more complete evidentiary record. Accordingly, the Court will not dismiss the complaint for failure to state a claim on statute of limitations grounds.

2. Fraudulent Concealment

Humana further contends that the doctrine of fraudulent concealment applies to toll the

limitations period. "[T]he statute of limitations may be temporarily tolled during such time that the perpetrator purposefully and successfully conceals [its] misconduct from its victim." *Álvarez-Maurás*, 919 F.3d at 626. A plaintiff may invoke fraudulent concealment by showing "1) wrongful concealment by defendants of their actions; and 2) failure of the [plaintiff] to discover, within the limitations period, the operative facts which form the basis of the cause of action; 3) despite the [plaintiff]'s diligent efforts to discover the facts." *Id*.

The requirements of Fed. R. Civ. P. 9(b)—that fraud be pleaded with particularity—apply to claims of fraudulent concealment. *See Epstein v. C.R. Bard, Inc.*, 460 F.3d 183, 189 (1st Cir. 2006) (holding that under Rule 9(b), "it is incumbent upon the plaintiff to plead with particularity the facts giving rise to the fraudulent concealment claim" (internal quotation marks and citation omitted)); *MSP Recovery Claims, Series LLC v. Warner Chilcott PLC*, 2019 WL 1333269, at *6 (D. Mass. Mar. 22, 2019) (rejecting as "conclusory" the assertion that "[a]ll applicable statutes of limitations have also been tolled by Defendants' knowing and active fraudulent concealment" (alteration in original) (citation omitted)).³

The issue of fraudulent concealment overlaps to a considerable extent with the issue of accrual under the discovery rule. Both require, among other things, that the plaintiff exercise reasonable diligence in investigating his or her potential claim. *See Gonzalez v. United States*, 284 F.3d 281, 292 (1st Cir. 2002) (fraudulent concealment requires that a plaintiff (1) "remains in ignorance of" a defendant's fraud (2) "without any fault or want of diligence or care on [its] part"); *Broderick*, 919 F. Supp. 2d at 182 ("[F]raudulent concealment requires not only that the defendant concealed crucial facts, but also that the plaintiff lacked the means to uncover these

³ Massachusetts state law requires proof of an affirmative act of fraud to establish fraudulent concealment. *See, e.g., Broderick v. PNC Fin. Serv. Grp.*, 919 F. Supp. 2d 178, 182 (D. Mass. 2013) ("In Massachusetts, fraudulent concealment generally requires an affirmative act of fraud.").

facts."); Salois v. Dime Sav. Bank of New York, FSB, 128 F.3d 20, 26 (1st Cir. 1997) ("[A]llegations of fraudulent concealment do not modify the requirement that plaintiffs must have exercised reasonable diligence.").

The complaint here does not plead fraudulent concealment with the necessary particularity under Rule 9(b). It simply alleges in general terms that "Biogen concealed its arrangements with CDF and TAF" and "did this while certifying to Humana that it was following federal law." (Compl. ¶ 86). That conclusory statement is not sufficient to satisfy the requirements of Rule 9(b). Accordingly, to the extent that Humana relies on a theory of fraudulent concealment to toll the running of the limitations period, the allegations of the complaint are inadequate.

B. <u>Federal Claims</u>

1. Count 1: RICO

a. General Principles

Count 1 alleges a substantive civil RICO violation. RICO makes illegal any "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *See Feinstein v. Resolution Tr. Corp.*, 942 F.2d 34, 41 (1st Cir. 1991) (citing 18 U.S.C. § 1962). "Racketeering activity" is defined in 18 U.S.C. § 1961(1) to include a variety of predicate offenses, including, among other things, violations of the mail-fraud statute, 18 U.S.C. § 1341, and the wire-fraud statute, 18 U.S.C. § 1343.⁴ The complaint here alleges both wire- and mail-fraud predicates.⁵

⁴ A "pattern of racketeering activity" means the commission of at least two related acts of racketeering activity during a period of ten years. 18 U.S.C. § 1961(5); see In re Lupron Mktg. & Sales Pracs. Litig., 295 F. Supp. 2d 148, 164 (D. Mass. 2003) (citing Schultz v. Rhode Island Hosp. Tr. Nat'l Bank, N.A., 94 F.3d 721, 731-32 (1st Cir. 1996)).

⁵ The complaint here also alleges that the predicate acts include "acts indictable under 18 U.S.C. [§] 1952 (use of interstate facilities to conduct unlawful activity)." (Compl. ¶ 98). Other than that passing reference, it contains no allegations concerning § 1952 or the specific elements of that offense. It is doubtful, to say the least,

The civil-suit provision of the RICO statute grants the right to sue to "[a]ny person injured in his business or property by reason of a violation of" the substantive provisions of the statute. 18 U.S.C. § 1964(c). Civil RICO claims "must be particularly scrutinized because of the relative ease with which a plaintiff may mold a RICO pattern from allegations that, upon closer scrutiny, do not support it." *Efron v. Embassy Suites (Puerto Rico), Inc.*, 223 F.3d 12, 20 (1st Cir. 2000). "[I]n cases alleging civil RICO violations, particular care is required to balance the liberality of the Civil Rules with the necessity of preventing abusive or vexatious treatment of defendants." *Miranda v. Ponce Fed. Bank*, 948 F.2d 41, 44 (1st Cir. 1991). "Civil RICO is an unusually potent weapon—the litigation equivalent of a thermonuclear device. The very pendency of a RICO suit can be stigmatizing and its consummation can be costly." *Id.*Accordingly, "courts should strive to flush out frivolous RICO allegations at an early stage of the litigation." *Figueroa Ruiz v. Alegria*, 896 F.2d 645, 650 (1st Cir. 1990).

b. The Indirect Purchaser Rule

The principal issue presented is whether Humana, as an indirect purchaser, has standing to assert a claim under the civil RICO statute.

Humana is (at least principally) a health insurer. It did not actually purchase any drugs from Biogen. Instead, it appears that in the normal course, (1) a physician would recommend or select a course of treatment for a patient that would include a Biogen prescription drug; (2) the prescription would be communicated from the physician's office to the patient's pharmacy; (3) the pharmacy would fill the prescription from its inventory; (4) the patient would pick up the drug at the pharmacy, either making a copay at that point or receiving a bill for the copay at a

whether the complaint plausibly alleges one or more predicate acts under § 1952, but defendants have not moved to dismiss on that basis.

later time; (5) the pharmacy would bill Humana for the remaining cost of the drug; and (6) Humana would pay the pharmacy.⁶ Although the complaint does not so allege, it appears that Biogen sold the drug to the pharmacy, either directly or through one or more layers of wholesalers or distributors. In any event, the complaint does not allege that Biogen sold the product directly to Humana.⁷

Humana is, therefore, an indirect purchaser. That status has substantial implications for its ability to bring a civil suit under the RICO statute—in particular, whether its claims are barred by the "indirect purchaser" rule.

(1) The Genesis of the Rule

The "indirect purchaser" rule is a doctrine developed by the Supreme Court in the antitrust context. A plaintiff asserting a claim under the Clayton Act cannot demonstrate an actionable injury if it only made indirect purchases. *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 737 (1977). The indirect purchaser rule is "a bright-line rule that authorizes suits by *direct* purchasers but bars suits by *indirect* purchasers." *Apple Inc. v. Pepper*, 139 S. Ct. 1514, 1520 (2019) (emphasis in original). The Supreme Court has explained that the reasons for barring indirect-purchaser suits are "(1) facilitating more effective enforcement of antitrust laws; (2) avoiding complicated damages calculations; and (3) eliminating duplicative damages against antitrust defendants." *Apple*, 139 S. Ct. at 1521, 1524.

The indirect purchaser rule applies in antitrust cases even in situations where the plaintiff contends that the full cost of the product—and therefore the full amount of any overcharge—had

 $^{^6}$ One of the three drugs, Tysabri, is administered intravenously. (Compl. ¶ 42). For the sake of simplicity, the Court will confine its discussion to prescription drugs dispensed through a pharmacy.

⁷ The manner in which Humana is compensated by the government may have a bearing on the nature and amount of any injury it may have suffered, but it appears to be irrelevant to the application of the indirect purchaser rule.

been passed on to it. *Kansas v. Utilicorp United, Inc.*, 497 U.S. 199, 216 (1990). The Supreme Court explained that "[a]lthough the rationales of . . . *Illinois Brick* may not apply with equal force in all instances, we find it inconsistent with precedent and imprudent in any event to create an exception" to the indirect purchaser rule. *Id.* at 208. The court recognized that proof of passed-on costs would overly burden antitrust litigation with complicated evidentiary questions. *Id.* at 216-17.

The civil-suit provision of RICO, 18 U.S.C. § 1964(c), which provides a right of action to "[a]ny person injured in his business or property by reason of" a violation of the statute, was modeled on the federal antitrust laws. Because of that, the Supreme Court held in *Holmes v*. Securities Investor Protection Corp., 503 U.S. 258, 267-68 (1992), that civil RICO plaintiffs are required to prove both but-for causation and proximate causation, as antitrust plaintiffs are required to do. See id. at 268 ("We may fairly credit the 91st Congress, which enacted RICO, with knowing the interpretation federal courts had given the words earlier Congresses had used first in § 7 of the Sherman Act, and later in the Clayton Act's § 4. It used the same words, and we can only assume it intended them to have the same meaning that courts had already given them." (citations omitted)); Hemi Grp., LLC. v. City of New York, 559 U.S. 1, 9 (2010).

Two subsequent Supreme Court decisions are also noteworthy. First, in *Bridge v*. *Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008), the court held that a plaintiff asserting a civil RICO claim predicated on mail fraud need not show that it relied on the defendant's alleged misrepresentation. The court reaffirmed that the civil RICO statute, having been modeled on the antitrust laws, required a plaintiff to prove both but-for and proximate causation. *Id.* at 654. It further held, however, that the proximate-cause requirement did not require first-party reliance on the alleged misrepresentation, provided that there was "a sufficiently direct relationship

between the defendant's wrongful conduct and the plaintiff's injury." *Id.* at 657. The court did not, however, address the indirect purchaser rule, or otherwise address the issue of standing.⁸

Second, in *Apple*, the Supreme Court reaffirmed the indirect purchaser rule in the context of an antitrust claim. Among other things, the court stated, as it had in *Utilicorp*, that the "bright-line rule of *Illinois Brick* means that there is no reason to ask whether the rationales of *Illinois Brick* apply with equal force in every individual case," and that the court "should not engage in an unwarranted and counterproductive exercise to litigate a series of exceptions." *Apple*, 139 S. Ct. at 1524 (internal quotation marks omitted).

Since the Court's decision in *Holmes*, two circuits, following its reasoning, have concluded that the indirect purchaser rule applies in all civil RICO actions. *See Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 616 (6th Cir. 2004); *McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 855 (3d Cir. 1996); *see also Carter v. Berger*, 777 F.2d 1173, 1177 (7th Cir. 1985) (adopting a similar conclusion in a case preceding *Holmes*). No circuit opinion has concluded otherwise.⁹

The First Circuit has yet to decide the issue. *See Marrero-Rolon v. Autoridad de Energia Electrica de P.R.*, 2016 WL 9459823, at *2 (D.P.R. Oct. 20, 2016) (certifying an interlocutory appeal regarding application of the indirect purchaser rule in the First Circuit), *appeal denied*, (1st Cir. Aug. 7, 2017).

⁸ The *Bridge* case did not arise in a typical commercial context, but from an alleged scheme to violate a "Single, Simultaneous Bidder Rule" imposed by a county in connection with the public auction of tax liens on delinquent taxpayers' property. The rule was intended to prevent any one buyer from obtaining a disproportionate share of the liens; the plaintiffs were disappointed bidders who contended that the actions of the defendants, who violated the rule, deprived them of their fair share of such liens. 553 U.S. at 642-44.

⁹ At least one circuit, without directly addressing the indirect purchaser rule, has concluded that civil RICO standing is governed by principles of proximate causation, so that if the alleged RICO violation was the proximate cause of the plaintiff's injury, the plaintiff had standing. *See Bivens Gardens Off. v. Barnett Banks of Fla.*, 140 F.3d 898, 906 (11th Cir. 1998). That interpretation conflates the concepts of standing and proximate causation, which are distinct, if overlapping, doctrines. *See Trollinger*, 370 F.3d at 612.

(2) The Neurontin Case

The issue is whether this Court should follow the lead of other courts and conclude that the RICO claim here is barred by the indirect purchaser rule. That question is complicated considerably by the First Circuit's decision in *In re Neurontin Marketing & Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013).

In *Neurontin*, a pharmaceutical company (Pfizer) engaged in unlawful marketing practices to boost off-label sales of a drug (Neurontin). A health insurer (Kaiser) brought suit under the civil RICO statute, alleging that it had incurred higher costs as a result of the inflated sales. *Id.* at 41. After a jury verdict in favor of Kaiser, Pfizer appealed.

On appeal, Pfizer argued that proximate causation had not been proved "because there are too many steps in the causal chain connecting its misrepresentations to the injury to Kaiser." *Id.* at 35.

The First Circuit, following *Holmes* and *Bridge*, held that plaintiff had proved both butfor and proximate causation. The court noted that under *Holmes*, proximate causation requires a "direct relation" between the RICO violation and the injury and that it should consider "three functional factors" to assess the existence of proximate causation. *Id.* at 35-36.

The court found that Pfizer's marketing activities had a direct relationship with Kaiser's injuries because they influenced the prescribing decisions of physicians, who do not pay for the drugs they prescribe. *Id.* at 39. Although Pfizer argued that physicians may have prescribed Neurontin for reasons other than its marketing, the court characterized that as "a damages question," not a proximate causation question. *Id.* And Pfizer's violation also satisfied the three functional factors in *Holmes*. First, Kaiser was able to present sufficient evidence to ascertain Pfizer's share of its damages. *Id.* at 38. Second, none of the other parties to whom Pfizer had made misrepresentations—physicians and formulary committee members—had paid money for a

Neurontin prescription. *Id.* at 37. Accordingly, there was no risk of multiple recovery. *Id.* Third, Kaiser was the party in the best position to enforce the law because it, unlike the other parties, had directly suffered economic injury from Pfizer. *Id.* at 38.

(3) Analysis

At first blush, *Neurontin* appears to be on all fours with this case: it involved a claim by a health insurer against a pharmaceutical company arising out of an unlawful scheme to promote sales of a drug, leading to unnecessary prescriptions and therefore increased payments. And the opinion addressed the issues of but-for and proximate causation in some detail, concluding that the requirements had been satisfied.

To the extent the issue here is one of proximate causation, the complaint appears to be sufficiently plausible to withstand a motion to dismiss. It pleads that there was a direct relationship between the injury claimed by Humana and the actions of defendants. Defendants contend that the independent decisions of doctors to prescribe MS drugs are an intervening cause that severed the link of proximate causation (as well as but-for causation). It is true that here, unlike in *Neurontin*, the complaint does not allege that defendants directly lobbied doctors to prescribe drugs. *See Neurontin*, 712 F.3d at 40-41. However, the complaint alleges that Biogen knew that its scheme would "capture patients because having begun a medication, patients are likely to stay on it." (Compl. ¶ 53). While that issue may pose difficult issues of proof, for present purposes, the complaint pleads the required direct relationship.

The three functional factors from *Holmes* also support a finding of proximate causation. Although Humana's damages may be difficult to prove, at this stage it is at least plausible that it will be able to present such proof. Humana is alleged to have been the target and victim of the alleged scheme, and therefore there may be little risk of multiple recoveries. And Humana is plausibly the party in the best position to enforce the law—better positioned, at least, than any

patients, physicians, pharmacy, or nonparty co-pay assistance programs.

The difficulty arises from the fact that the *Neurontin* court addressed only the issues of but-for and proximate causation; it did not address the indirect purchaser rule, or indeed the question of standing, at all. Proximate causation and standing are distinct, if overlapping issues. As the Sixth Circuit has explained:

Like the antitrust laws, RICO's civil-suit provision imposes two distinct but overlapping limitations on claimants—standing and proximate cause. Standing poses a threshold question involving constitutional, prudential and (as in this case) statutory limitations on who may sue, regardless of the merits of that person's claim. Proximate cause poses a merits question involving common-law and prudential limitations on the consequences for which the law will hold a defendant accountable, regardless of the plaintiff's standing to sue.

Trollinger, 370 F.3d at 612 (citations omitted). The court went on to observe:

[T]he two concepts overlap and that is particularly true in the context of civil RICO claims. As a general matter, they overlap because a plaintiff who lacks standing to vindicate a derivative injury also will be unable to show proximate cause. And as a matter of RICO law, the two concepts overlap because they both grow out of the "by reason of" limitation in RICO—namely, the requirement that claimants establish that their injury was "by reason of" a RICO predicate act violation. The "by reason of" limitation, in other words, bundles together a variety of "judicial tools," some of which are traditionally employed to decide causation questions and some of which are employed to decide standing questions.

Id. at 613.

Presumably, the *Neurontin* court did not address the issue of standing, or the indirect purchaser rule, because the defendant pharmaceutical company did not raise it. And this Court cannot, of course, assume that the *Neurontin* court implicitly considered the standing issue and rejected it. *Neurontin* therefore is not controlling precedent as to the question of standing and the potential application of the indirect purchaser rule. Nonetheless, in light of its rough similarities to the present case, the opinion gives this Court considerable pause.

The court in *Humana*, *Inc. v. Indivior Inc.*, 2021 WL 3101593 (E.D. Pa. July 22, 2021),

faced a somewhat analogous situation. *Indivior* involved a civil RICO claim by a health insurer (Humana) against a pharmaceutical company (Indivior) for unlawful promotion of a drug, resulting in reimbursement for medically unnecessary prescriptions and the payment of higher prices for the drug. As here, the defendants moved to dismiss the RICO claim on the ground that Humana was an "end payor[] or indirect purchaser[] in the distribution chain who [paid] for drugs purchased by a pharmacy, wholesaler, or [its] insured," and that therefore the claims were barred by the indirect purchaser rule. *Id.* at *7 (internal quotation marks omitted).

In resolving that issue, the district court had to address a potential conflict between two Third Circuit opinions: *McCarthy*, 80 F.3d at 851-55, which held that the indirect purchaser rule applied to all civil RICO claims, and *In re Avandia Marketing Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015), which upheld a civil RICO claim by third-party payors (union health and welfare funds) against a drug manufacturer arising out of unlawful conduct that increased sales. *Indivior*, 2021 WL 3101593, at *9. Among other things, the court concluded that *Avandia* addressed only the issue of proximate causation; that the "concepts or standing under the indirect purchaser rule and proximate causation" were distinct; and therefore *Avandia* did not disturb the conclusion of *McCarthy* that "an indirect purchaser/end-payor lacks standing to pursue RICO claims." *Id.* at *10.¹⁰ And the court noted that other district courts in the Third Circuit had reached similar conclusions. *See, e.g.*, *Hu v. BMW of N. Am. LLC*, 2021 WL 1138123, at *3 (D.N.J. Mar. 24, 2021).

Following that reasoning, while *Neurontin* is controlling as to the issue of but-for and proximate causation, it is not as to the application of the indirect purchaser rule. The question,

¹⁰ The *Indivior* court also distinguished *Avandia* on its facts, on the ground that the alleged injury there was "based on their inclusion of the product at issue in their formulatory decisions at favorable rates rather than covering the competitor's less expensive drugs." *Indivior*, 2021 WL 3101593, at *10.

then, is whether this Court should apply that rule here.

The argument in favor of applying the rule is straightforward. According to the three circuits that have considered the issue, that result is dictated by statutory history and the Supreme Court's jurisprudence. *See, e.g., McCarthy*, 80 F.3d at 855 ("Significantly, antitrust standing principles apply equally to allegations of RICO violations. The precepts taught by *Illinois Brick* and *Utilicorp* apply to RICO claims, thereby denying RICO standing to indirect victims." (citations omitted)). Put simply, if the indirect purchaser rule applies to claims under § 4 of the Clayton Act, it necessarily applies to civil RICO claims under § 1964(c). And because the rule has no exceptions in the antitrust context—even where, as a practical matter, it means that a violation will go unremedied—it likewise has no exceptions in the civil RICO context.

There are, to be sure, potential pathways around the application of the rule. One is to conclude that Humana is not, in fact, an indirect purchaser. The problem with that is that it does not appear to be true: Humana is an insurer, and there is no allegation in the complaint that it actually paid anything directly to Biogen. Another is to conclude that the question of standing is subsumed within the question of proximate causation. Although the Eleventh Circuit seems to have reached such a conclusion in *Bivens Gardens*, 140 F.3d at 906, it did so without any real analysis, and that reasoning would simply conflate the doctrines of standing and proximate cause into a single inquiry.

Finally, the Court could take a direct approach—based on the practical realities of the health-care marketplace and the nature of the claim asserted here—and formulate an exception to the indirect purchaser rule, or perhaps conclude that the rule should not apply at all in civil RICO actions outside the antitrust context. While that approach has some superficial appeal, that, too, is problematic.

It is certainly true that the concept of a "purchaser" does not transfer neatly from the antitrust context to the health-care context. Antitrust cases typically involve a marketplace scenario with multiple levels, with payment for and title to goods passing from one participant to another at each level—for example, a manufacturer sells to a wholesaler, who sells to a retailer, who sells to a customer. In the antitrust marketplace, therefore, the ultimate consumer makes the decision to buy a product, pays for it, and uses it.

In the prescription-drug marketplace, those purchasing functions are normally split three ways: the physician effectively makes the decision to buy the product; the health insurer effectively pays for it (although the patient is required to make a copay); and the patient owns and uses it.¹¹ For that reason, in the prescription-drug marketplace, a scheme to defraud often targets the government or third-party payors—the entities that actually pay for the drugs at issue.

The theory of the injury here likewise does not neatly align with a normal antitrust marketplace scenario, in which the monopolist sets an artificially high price. Instead, the core allegation appears to be that the medication was over-prescribed.¹² Specifically, it alleges that some portion of the patient population would have used a different type of therapy, such as one provided by a Biogen competitor.¹³ In other words, the theory of the complaint seems to be that

¹¹ Other factors may complicate the analysis: for example, the potential ability of a pharmacist to substitute a generic or similar product, or the potential ability of an insurer to negotiate prices directly with the drug manufacturer. And here the facts alleged in the complaint appear to suggest a more complex process than usual for dispensing of the drugs to the patient. For example, the complaint alleges that ACS is a "specialty pharmacy that also provides patient-management services to the pharmaceutical industry." (Compl. ¶ 13). How, if at all, it performed any role in purchasing or dispensing the drugs to patients is not set out in the complaint. Furthermore, and as noted, Tysabri is infused intravenously by a medical provider at a location such as a hospital, doctor's office, or infusion center. (*Id.* ¶¶ 42, 84). Presumably, the dispensing of that medication, and its billing, does not follow the typical pattern for prescription drugs.

¹² The complaint does *not* allege that any drugs were prescribed to patients for whom they were medically unnecessary. Nor does it seem to allege that patients who needed treatment for MS, and could not afford the copays, should have been left to suffer without such treatment.

¹³ The complaint is short on detail as to those alternate therapies, including their availability, cost, and effectiveness. Instead, it simply makes three vague references to "cheaper alternatives," (Compl. ¶ 6), "less expensive MS therapies, including generic drugs," (*id.* ¶ 56), and "other multiple sclerosis drugs," (*id.* ¶ 94). And it

some number of qualified candidates who needed MS therapy were diverted to Biogen therapies from less-expensive alternate therapies provided by another company.¹⁴

The complaint also alleges that Biogen "inflate[d] both the number and price of prescriptions for MS Drugs," leading to artificially inflated "price reimbursements by third-party payors," including "private insurers of Medicare Part D and Medicare Advantage [Part C] plans," such as plaintiff. (Compl. ¶¶ 2, 4); (see id. ¶ 83 ("But for the scheme, Humana would have paid for fewer MS Drugs prescriptions (and associated costs of administering the drug), and it would have paid less for each covered prescription.")). It is unclear precisely what is meant by that—whether the alleged higher prices were solely due to the unnecessary prescription of expensive medications, or whether the prices were somehow inflated on top of that. If it is the latter, the theory of the complaint is much closer to an antitrust-type injury, in which higher prices charged by Biogen were passed on to wholesalers and distributors, pharmacies, and ultimately Humana.

To the extent, however, that the theory of injury is that the scheme caused the writing of a greater number of expensive prescriptions, the wholesaler (the direct purchaser) may have no

is silent as to the interchangeability (if any) of those therapies and the roles of the physician, the pharmacist, and the patient in selecting a precise type (or brand) of drug a patient will take.

¹⁴ To illustrate the concept, consider two hypothetical drugs: an expensive alternative ("Cadillac") and a cheaper alternative ("Chevrolet"). The normal result of an antitrust violation is the charging of an unfairly high monopolistic price, so that the "Chevrolet" is priced like a BMW, and the "Cadillac" is priced like a Rolls-Royce. Those higher prices are typically passed on from the monopolistic manufacturer to the wholesaler (the direct purchaser), and from there to the retailer and the consumer (the indirect purchaser). Under that scenario, and according to the indirect purchaser rule, only the direct purchaser (the wholesaler) has standing to sue under the antitrust laws.

Here, by contrast, the claim is not (or does not seem to be) that the prices of the "Cadillacs" and the "Chevrolets" were inflated by the unlawful behavior. Rather, the claim is that the mix of prescriptions was altered, so that too many "Cadillac" prescriptions were written—to use hypothetical percentages, the mix should have been 50% "Cadillacs" and 50% "Chevrolets," but instead was 75% "Cadillacs" and only 25% "Chevrolets."

¹⁵ The complaint alleges that Humana paid higher costs in connection with the intravenous administration of Tysabri, which are not higher costs for the drug *per se*, but higher associated costs. (Compl. ¶ 84).

incentive to file suit against the drug manufacturer. The wholesaler is selling a higher quantity of the expensive drugs, probably at a higher margin than the cheaper alternatives, and likely has suffered no injury. Instead, it is the payors—the health insurer and the patients—who are the injured parties. And because the scheme here compensated the patients by making their copayment, the insurer may be the only injured party.

In any event, while there may be reasons to carve out an exception to the indirect purchaser rule, or to conclude that it should not apply, such a decision is fraught with policy judgments that are more properly committed to the Court of Appeals rather than a single District Judge. Under the circumstances, this Court will follow the lead of every circuit to have considered the issue, and apply the indirect purchaser rule.

Accordingly, because Humana is an indirect purchaser of the pharmaceutical products at issue in this case, it does not have standing to assert a civil RICO claim. Count 1 will therefore be dismissed.

c. Adequacy of RICO Allegations

For the sake of completeness, the Court will address two additional issues that warrant dismissal of the RICO claims, independent of the standing issue.

(1) Predicate Offenses – Mail and Wire Fraud

(a) Mail and Wire Fraud Generally

As noted, the RICO claim here is based on predicate acts of mail and wire fraud. The mail-fraud statute prohibits the use of the mails in connection with a "scheme or artifice to defraud." 18 U.S.C. § 1341. "To establish the commission of this offense, the government must show a scheme to defraud using false pretenses, the defendant's knowing and willing participation in the scheme with the intent to defraud, and the use of the mails in furtherance of that scheme." *United States v. Simon*, 12 F.4th 1, 33 (1st Cir. 2021). The wire-fraud statute

differs only in that the government must prove the use of a wire in interstate or foreign commerce in furtherance of the alleged scheme. 18 U.S.C. § 1343; *Simon*, 12 F.4th at 33.

Both statutes require the use of the mails or wire facilities in furtherance of the scheme to defraud. "The 'in furtherance' requirement is to be read broadly." *Simon*, 12 F.4th at 33. The government need not show that the mail or wire communication actually contains the fraudulent misrepresentation, only "that the mailing was 'incident to an essential part of the scheme." *Id*.

(b) Application of Rule 9(b)

Civil RICO claims based on predicates of mail or wire fraud must meet the heightened pleading standard of Rule 9(b). Accordingly, for civil RICO claims, "under Rule 9 'the pleader is required to go beyond a showing of fraud and state the time, place and content of the alleged mail and wire communications perpetrating that fraud." *Cordero-Hernandez v. Hernandez-Ballesteros*, 449 F.3d 240, 244 (1st Cir. 2006) (internal quotation marks omitted) (quoting *North Bridge Assocs., Inc. v. Boldt*, 274 F.3d 38, 43 (1st Cir. 2001)); *see Ahmed v. Rosenblatt*, 118 F.3d 886, 889 (1st Cir. 1997) (noting that it is "well settled law in this circuit that RICO pleadings of mail and wire fraud must satisfy the particularity requirements of Rule 9(b)"); *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996)) ("Rule 9 imposes a heightened pleading requirement for allegations of fraud in order to give notice to defendants of the plaintiffs' claim, to protect defendants whose reputation may be harmed by meritless claims of fraud, to discourage 'strike suits,' and to prevent the filing of suits that simply hope to uncover relevant information during discovery.").

Thus, for example, in *Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 42 (1st Cir. 1991), the First Circuit affirmed the dismissal of a civil RICO claim based on mail and wire fraud predicates where the complaint failed to comply with Rule 9(b). *Id.* at 42. The court noted

that the complaint alleged mail and wire fraud violations in general terms, but did not "supply any additional detail as to when the [mail and wire] communications occurred, where they took place, or what they contained." *Id*.

Absent this rudimentary information, the complaint fell measurably short of meeting Rule 9(b)'s specificity requirement. It is not enough for a plaintiff to file a RICO claim, chant the statutory mantra, and leave the identification of predicate acts to the time of trial.

Id.; *see also Ahmed*, 118 F.3d at 889 (noting that the complaint did not meet the requirements of Rule 9(b) because it "contains only the bald assertion that the defendants (unspecified) used the U.S. mails to fraudulently convey their interests in [plaintiff's] properties, that the defendants (again unspecified) used the U.S. Postal Service by mailing unspecified materials, and that the defendants used wire communications"). ¹⁶

(2) Allegations of Mail or Wire Communications

The allegations in the complaint concerning the use of mails or interstate wires consist, in their entirety, of the following:

Throughout the relevant period, Biogen, ACS, CDF, and TAF used thousands of mail and interstate wire communications to create and manage their scheme, which involved nationwide distribution of the MS Drugs through ACS at the direction of Biogen. Biogen communicated with ACS, US Bioservices, and the

¹⁶ Similarly, in *Metropolitan Property & Casualty Insurance Co. v. Savin Hill Family Chiropractic, Inc.*, 2016 WL 11004383 (D. Mass. June 15, 2016), the court observed:

Because the Plaintiffs' fraud, RICO and conspiracy claims all rely upon allegations that the Defendants engaged in a fraudulent scheme to inflate medical bills submitted to Metropolitan and Commerce, they must plead with particularity specific individual bills which are fraudulent based on particular facts alleged, e.g., on a certain date a bill sought payment for spinal manipulations not performed as evidenced by the patient's assertion that she received no such treatment.

Id. at *3. The court noted that the complaint came close to pleading with the requisite specificity that certain medical bills were premised on material misrepresentations, because those allegations contained the name of the chiropractor defendant who recorded administering treatment that was not rendered, the initials of the Metropolitan claimant, the claim number, and the date of loss. Id. In some instances, the allegations also contained the date of the purported treatment. Id. That is, the "alleged misrepresentations identif[ied] who made the misrepresentations, what the misrepresentations were, where the misrepresentations in recording and billing were made, and when they occurred." Id. But the "critical missing component" was the specificity regarding the bills that resulted from the misrepresentations. Id. The opinion noted that the complaint needed to identify with particularity the fraudulent bills arising from the misrepresentations alleged. Id. at *3-4.

foundations through the mail and wires, causing thousands of reimbursement requests to be submitted to Humana over the wires or by mail, and used the wires and mail to effectuate their receipt of payments and contributions. For example, from 2011 through 2019, ACS submitted requests to Humana for reimbursement of more than 76,000 prescriptions worth nearly \$350 million for the MS Drugs using the wires or the mail.

(Compl. ¶ 80).

False representations of compliance with federal and state laws were made to Humana for payment over the wires or by mail. These false representations were made directly to Humana and were a condition of reimbursement for all the MS Drugs claims submitted to Humana. The illegally obtained payments were sought through, and sent over, the wires or by mail. The claims for reimbursement submitted for payment to Humana over the wires or by mail identified in Exhibit A attached to this Complaint are examples of the MS Drugs Enterprise's fraud on Humana.

 $(Id. \ \P \ 95).$

Defendants and their co-conspirators have sought to and have engaged in the commission of overt acts, including the following unlawful racketeering predicate acts:

- a. Multiple instances of mail fraud in violation of 18 U.S.C. §§ 1341 and 1346; and
- b. Multiple instances of wire fraud in violation of 18 U.S.C. §§ 1343 and 1346.

(*Id.* \P 109).

Exhibit A to the complaint, which is identified in Paragraph 95, is captioned "Examples of 100 Biogen Subsidized Copayments." It has four columns, labeled "Rx Fill Date," "Copay Foundation," "Drug Cost," and "Copay Subsidy." Beneath those headings, respectively, are a date (for example, "1/7/2011"), the name of one of the foundations (either The Assistance Fund or the Chronic Disease Fund), the cost of the drug (for example, "\$6,982.21"), and the amount of the copay (for example, "\$997.30").

Apart from Exhibit A, the complaint clearly fails to state the mail and wire fraud

predicates with the requisite detail. Courts have routinely held that generalized statements concerning mailings or wire communications are not sufficient to satisfy the pleading requirements. *See, e.g., Feinstein*, 942 F.2d at 42. Thus, for example, the general allegation that "Biogen, ACS, CDF, and TAF used thousands of mail and interstate wire communications to create and manage their scheme" does not reveal which specific defendant or entity made the communications, when they were made, what they contained, or even whether they were made by mail or wire. (*See* Compl. ¶ 80).

The mail and wire fraud predicates thus rest entirely on the adequacy of Exhibit A. Notably, Exhibit A does not specifically identify which (if any) of the communications were made by mail, and which were made by wire; Paragraph 95, which describes Exhibit A, uses a disjunctive phrase to describe all 100 communications: "[t]he claims for reimbursement submitted for payment to Humana *over the wires or by mail* identified in Exhibit A . . . are examples of the MS Drugs Enterprise's fraud on Humana." (*Id.* ¶ 95 (emphasis added)). And Exhibit A contains no detail as to who sent the communications (other than "Humana's own specialty pharmacy"). (*See id.* ¶ 85). It does not even allege the technical requirement of the wire-fraud statute, that the communication be transmitted "in interstate or foreign commerce." *See* 18 U.S.C. § 1343.

The absence of further detail in Exhibit A is particularly puzzling, in that the communications in question were apparently made by a Humana subsidiary ("Humana's own specialty pharmacy") to Humana itself. (Compl. ¶ 85).¹⁷ And there are no specifics whatever as

¹⁷ For that reason, there is no basis to apply a "more flexible" pleading standard, as may be appropriate when critical information is in the custody of the defendant or a third party. *See, e.g., United States v. Regeneron Pharms., Inc.*, 2020 WL 7130004, at *15 (D. Mass. Dec. 4, 2020) (applying a more flexible standard in a case involving claimed violations of the False Claims Act and Anti-Kickback Statute because it was alleged that defendant caused a third party to submit a false claim to the government, rather than submitting the claim itself). Similarly, there is no basis to permit Humana leave to amend, as may be the case when the critical information is not in the plaintiff's possession. *See New England Data Servs., Inc. v. Becher*, 829 F.2d 286, 290-92 (1st Cir. 1987)

to any communications between ACS and Humana, despite the fact that the complaint expressly alleges that "from 2011 through 2019, ACS submitted requests to Humana for reimbursement of more than 76,000 prescriptions worth nearly \$350 million for the MS Drugs using the wires or the mail." (Id. ¶ 80). Regardless, the complaint does not allege a single specific instance of a mail or interstate wire communication—at best, it only alleges that certain specific communications were sent by "the wires or by mail." (E.g., id. ¶ 95).

(3) Allegations of Misrepresentation

The theory of fraudulent misrepresentation alleged in the complaint is that defendants "caused the submission of false certifications to Humana . . . causing it to pay millions of dollars in reimbursements for the MS Drugs that Humana would not have otherwise paid." (Id. ¶ 8). More specifically, the complaint alleges:

False representations of compliance with federal and state laws were made to Humana for payment over the wires or by mail. These false representations were made directly to Humana and were a condition of reimbursement for all the MS Drugs claims submitted to Humana.

(*Id.* ¶ 95; *see id.* ¶ 35 ("In order to effectuate their scheme . . . Defendants misrepresented to Humana that they were complying with state and federal law, including laws related to kickbacks and false claims"); *id.* ¶ 50 (alleging that the scheme included "misconduct specifically directed to Humana: namely, specific misrepresentations that those participating in the deceptive scheme were complying with the very laws that they were in fact flouting")).

⁽holding that because of the "difficulties in specifically pleading mail and wire fraud as predicate acts," the district court should make a "determination as to whether the claim as presented warrants the allowance of discovery," and if so, should "provide an opportunity to amend the defective complaint," and stating that one of the factors to consider is whether "the specific information as to use is likely in the exclusive control of the defendant").

Two additional paragraphs suggest that the certifications were set forth, at least in part, in one or more contracts between Humana and Biogen and/or ACS:

Biogen and its agent ACS made such certifications [of compliance with state and federal law] and therefore directly misrepresented to Humana that they were not inducing Medicare patients to take Biogen's drugs by subsidizing copayments, and that Biogen and ACS were otherwise complying with federal law. Biogen also made contractual representations to Humana in connection with its non-Medicare insurance policies that it would comply with the laws including, among others, those related to fraud, abuse, and prohibiting kickbacks.

(*Id.* ¶ 36).

Humana's agreements with its providers include a provision that requires the provider to certify its compliance with state and federal law, as well as rules promulgated by government entities such as CMS. These contractual provisions are essential for Humana to ensure that it receives prompt payments and reimbursements from CMS for valid claims, and to ensure that it does not pay invalid claims that might increase costs to both itself and Medicare. Humana also relies on these representations in approving not only Medicare, but also commercial insurance claims and claims under other plan types for payment.

(*Id.* ¶ 38).

In addition, Paragraphs 135 and 136 of the complaint—which are part of Count 6, the claim for breach of contract, but not expressly incorporated in the RICO claim—allege that Humana and Biogen entered into a contract with an effective date of January 1, 2006, "in which Humana promised to cover Biogen's MS Drugs on its commercial (non-Medicare) insurance formulary and provide it with a preferred position" in exchange for Biogen's promise to pay rebates on purchases. (*Id.* ¶ 135). As part of that 2006 contractual agreement, Biogen agreed to "comply with any and all applicable federal, state and local laws, regulations and ordinances," including those concerning "health care anti-fraud and abuse laws." (*Id.* ¶ 136).

Accordingly, the alleged falsehoods at issue are not that the prescriptions themselves were phony, or that the treatment was medically unnecessary; rather, it is the representation, in one or more "certifications," that defendants were in compliance with the law.

To be clear, the theory of the complaint is *not* that Biogen (or ACS) made misrepresentations to the federal government (or to physicians or pharmacies), and that those misrepresentations to others were the proximate cause of harm to Humana. *See Bridge*, 553 U.S. at 649 (first-party reliance is not an element of proximate causation in a private RICO claim predicated on mail fraud); *Neurontin*, 712 F.3d at 36-37 (same). Rather, it is that Biogen (and ACS) made misrepresentations "*directly*" to Humana. (*See, e.g.*, Compl. ¶ 36). ¹⁸

The misrepresentations at issue are thus alleged to be certifications, made directly to Humana, that Biogen and ACS were in compliance with federal law. Nonetheless, although those certifications are at the very heart of the RICO claim, the complaint does not state when they were made and how they were made, and does not provide the actual language of the misrepresentations at issue.

To the extent the complaint alleges in general terms that Biogen and ACS made certifications of compliance to Humana—or, more vaguely, that certifications "were made," (Compl. ¶ 95)—it does not appear to comply with the requirements of Rule 9(b). Those allegations describe who made the fraudulent communications (Biogen and ACS), their general content (certifications of compliance with federal, state, and local law), and the recipient (Humana). But they say nothing about the time or place of the communications, their specific content, or even how many such communications took place. *See Cordero-Hernandez*, 449 F.3d

¹⁸ The complaint also contains the following allegation: "CMS regulations require 'downstream' entities [defined to include "pharmacies dispensing medication and manufacturers selling medication," (Compl. ¶ 28)] that generate and submit PDE [Prescription Drug Event] claims data ["a condition of payment for CMS's provision of Medicare funds to Part D Plan sponsors," (*Id.* ¶ 27)] to certify that such data is true, accurate, and complete and that the PDE data is the basis for obtaining federal reimbursement for the healthcare products or services reflected therein." (*Id.* ¶ 29). But the complaint alleges elsewhere, on multiple occasions, that the relevant misrepresentations were made by Biogen or ACS "directly" to Humana—*not* that they were made by Biogen, ACS, or other entities to CMS. The relevance of that allegation is therefore far from clear. And although the complaint alleges that "downstream" entities who participate in Part C are required to comply with the law, (*id.* ¶ 30), there is no parallel allegation that those entities are required to make a similar certification.

at 244 (noting that complaint alleging wire fraud failed to make "the requisite allegations identifying specific interstate phone calls by time, place, and content"); *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006) (requiring plaintiff to provide *some* "representative examples of [defendants'] alleged fraudulent conduct, specifying the time, place, and content of their acts and the identity of the actors"). *But see Humana Inc. v. Mallinckrodt ARD LLC*, 2020 WL 3041309, at*10 (C.D. Cal. Mar. 9, 2020) (concluding, without analysis, that false certifications of compliance with state and federal law sent to Humana were sufficient to satisfy Rule 9(b)). ¹⁹

There is one place in the complaint where the alleged misrepresentation is pleaded in somewhat greater detail. As noted, Paragraphs 135 and 136—which, as a technical matter, are not pleaded under the RICO counts—allege that Biogen and Humana entered into a contract with an effective date of January 1, 2006, that contained a provision in which Biogen agreed that it "shall comply" with applicable federal laws. That allegation supplies, at least in rough terms, an approximate time and place of the alleged communication. And Paragraphs 36 and 38 refer (albeit vaguely) to contractual provisions applicable to Biogen, which apparently refer to the 2006 contract.

¹⁹ *Mallinckrodt* involved a claim by Humana against a pharmaceutical manufacturer alleging an unlawful co-pay scheme similar in many respects to the claim asserted here. The complaint alleged, among other things, that the defendant "directly misrepresented" to Humana that it was "complying with state and federal law, including laws related to bribery, kickbacks, and false claims," when it submitted data for prescription drug event ("PDE") claims "certifying that such data is true, accurate, and complete." *Id.* at *10. The court's Rule 9(b) analysis was as follows:

Defendant asserts in conclusory fashion that this allegation lacks sufficient particularity to satisfy Rule 9(b). Plaintiff has alleged that each time Defendant certified that it was in compliance with federal and state laws, it knowingly made a false statement because it knew at the time it made the statements that its co-pay assistance violated federal statutes and its doctor payments violated state law. This is sufficient.

Id. (internal quotation marks and citation omitted). The *Mallinckrodt* court also denied a motion to dismiss the civil RICO claims without addressing the indirect purchaser rule, holding only that the complaint was sufficient to satisfy the but-for and proximate causation requirements. *Id.* at *14-16.

The complaint does not include any allegations as to how Humana's contractual relationship with Biogen for its private commercial insurance business has any relevance to the alleged scheme at issue here. And if the critical misrepresentation is set forth in a contract, there is no obvious reason why the complaint cannot allege the actual date of the contract and the precise contractual language. Accordingly, while the allegations in Paragraphs 135 and 136 are more specific than the general allegations found elsewhere in the complaint, they do not appear to have any clear connection to the alleged scheme to defraud.

(4) <u>Conclusion</u>

The lack of specificity in the complaint as to those issues, taken as a whole, is sufficient to warrant dismissal of Count 1. They may amount to no more than violations of technical pleading requirements, but that is what the rules—at least the rules for pleading a civil RICO action with mail and wire fraud predicates—require. And because they concern matters that are, or ought to be, within the knowledge of Humana, there is no apparent reason why this Court should overlook the omissions or permit Humana to fill in the gaps after a period of discovery. Accordingly, on that additional ground, Count 1 fails to state a claim upon which relief can be granted.

2. <u>Count 2: RICO Conspiracy</u>

Because the complaint fails to plead a substantive RICO claim, its claim for conspiracy to commit RICO must also be dismissed. *See Efron*, 223 F.3d at 21 (holding that if the pleadings fail to state a substantive RICO claim, then the conspiracy claim also fails); *Langan v. Smith*, 312 F. Supp. 3d 201, 205 (D. Mass. 2018) (same).

C. Supplemental Jurisdiction

In light of the dismissal of Counts 1 and 2, the Court will decline to exercise supplemental jurisdiction over the remaining claims. Where a complaint fails to state a viable

claim under federal law and jurisdiction over the remaining claims is based solely on

supplemental jurisdiction, 28 U.S.C. § 1367, a "district court has discretion to decline to exercise

supplemental jurisdiction." Uphoff Figueroa v. Alejandro, 597 F.3d 423, 431 n.10 (1st Cir.

2010); 28 U.S.C. § 1367(c). In so doing, the court "must take into account considerations of

judicial economy, convenience, fairness to the litigants, and comity." Delgado v. Pawtucket

Police Dep't, 668 F.3d 42, 48 (1st Cir. 2012); see Wilber v. Curtis, 872 F.3d 15, 23 (1st Cir.

2017) ("[I]t can be an abuse of discretion—if no federal claim remains—for a district court to

retain jurisdiction over a pendent state law claim when that state law claim presents a substantial

question of state law that is better addressed by the state courts.").

Here, the two federal claims have been dismissed. What remains are 52 state-law claims,

brought under the laws of 30 states. Apart from the complaint and motions to dismiss, no

substantial litigation has occurred. Under the circumstances, the Court will decline to exercise

supplemental jurisdiction over the remaining state-law claims.

IV. Conclusion

For the foregoing reasons, the motions of defendants Biogen, Inc., and Advanced Care

Scripts, Inc., to dismiss for failure to state a claim upon which relief can be granted are

GRANTED as to Counts 1 and 2. The Court declines to exercise supplemental jurisdiction over

the claims set forth in Counts 3 through 10, which are accordingly DISMISSED without

prejudice.

So Ordered.

/s/ F. Dennis Saylor IV

F. Dennis Saylor IV

Chief Judge, United States District Court

Dated: March 31, 2023

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